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10/827,073	04/19/2004	Rajiv Doshi	DOSHI.001C1	1880
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3743

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/827,073

Applicant(s)

DOSHI, RAJIV

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 26-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/12/05

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment/Arguments***

1. Applicant's arguments filed 10/4/05 have been fully considered but they are not persuasive.
2. In response to Applicant's arguments regarding the limitation "configured to fit substantially within..." it should be noted that Applicant has not limited the recitation to how much of the device fits into the mouth, i.e., the term substantially is a broad recitation and as such the Roy reference teaches a device that fits substantially within the mouth.
3. In response to applicant's argument that Roy does not teach a device that substantially fits within a mouth, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-10, 12-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Roy (US 4,601,465).

3. **As to claim 1**, Roy teaches a device for treating a patient with a breathing disorder, the device configured to be held in a patient's mouth and comprising at least one aperture (**See Figs. 1-6**) providing fluid communication between an inside and an outside of the patient's mouth through the mouthpiece, the device further comprising an obstructing member (**See Figs. 2, 3, 4, 6**) that obstructs at least a portion of the aperture, the obstructing member configured to limit exhalation air flow more than inhalation air flow through the aperture (**See Col. 2, lines 25-50**).

4. **As to claim 2**, Roy teaches a device wherein the device is configured to be used by a sleeping patient.

5. **As to claim 3**, Roy teaches a device wherein the device is configured to be held between a patient's jaws (via elements **15**).

6. **As to claim 4**, Roy teaches a device wherein the obstructing member is configured to reduce an open area of the aperture by a pre-determined amount (**See Col. 2, lines 25-50**).

7. **As to claim 5**, Roy teaches a device wherein the obstructing member is configured to allow air to flow thorough a small area of the aperture in an exhalation direction and through a larger area of the aperture in an inhalation direction (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**).

8. **As to claim 6**, Roy teaches a device wherein the larger area overlaps the small area (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**).

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9. **As to claim 7**, Roy teaches a device wherein the obstructing member is further configured to allow exhalation air to flow through an area that is larger than the small area when an exhalation air pressure exceeds a predetermined value (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**).

10. **As to claim 8**, Roy teaches a device for use in treating a patient with a breathing disorder, the device comprising a body defining an inside surface and an outside surface and configured to be held in a patient's mouth; the body comprising an aperture (**See Figs. 1-6**) in a front portion thereof, the aperture providing fluid communication between the inside surface and the outside surface; and a valve device (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**) configured to limit expiratory fluid flow directed from the inside surface to the outside surface more than inspiratory fluid flow from the outside surface to the inside surface.

11. **As to claim 9**, Roy teaches a device wherein the body is substantially entirely held within the patient's mouth.

12. **As to claim 10**, Roy teaches a device, wherein the body is substantially U-shaped (**See Fig. 1**).

13. **As to claim 12**, Roy teaches a device, wherein the aperture has a first area and a second area that is larger than the first area, wherein the valve device is configured to permit fluid flow through only the first area in a direction from the inside surface to the outside surface, and through both the first area and the second area in a direction from the outside surface to the inside surface (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**).

14. **As to claim 13**, Roy teaches a device, wherein the second area overlaps at least a portion of the first area (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**).

15. **As to claim 14**, Roy teaches a device, wherein the valve device is further configured to allow fluid flow through a third area that is larger than the first area when a pressure of expiratory fluid flow exceeds a threshold value (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**).

16. **As to claim 15**, Roy teaches a device, wherein the valve device comprises a movable element pivotably joined to a fixed element that is immovably attached to the body (**See Figs. 4 and 6**).

17. **As to claim 16**, Roy teaches a device, wherein the movable element is joined to the fixed element by a hinge (**the Examiner considers the hinge to be a living hinge, See Figs. 4 and 6**) with a pivot axis lying in a plane substantially parallel to the outside surface.

18. **As to claim 17**, Roy teaches a device, wherein the movable element comprises a flap (**See Figs. 4 and 6**) that occludes at least a portion of the aperture.

19. **As to claim 18**, Roy teaches a device, wherein the flap is secured to the fixed element so as to allow the flap to pivot only inwards (**See Figs. 4 and 6**).

20. **As to claim 19**, Roy teaches a device, wherein the flap is made of a substantially flexible material **33,39**.

21. **As to claim 20**, Roy teaches a device for treating a patient with a breathing disorder, the device comprising: a housing configured to be held in a patient's mouth,

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the housing enclosing at least one valve (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**) configured to create a first flow resistance to inspiration and a second flow resistance to expiration, wherein the first flow resistance is less than the second flow resistance.

22. **As to claim 21**, Roy teaches a device, wherein the valve is further configured to create a third flow resistance to expiration when a pressure of said expiration exceeds a threshold pressure (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**).

23. **As to claim 22**, Roy teaches a device, wherein the valve comprises a flap (**See Figs. 4 and 6**).

24. **As to claim 23**, Roy teaches a device, wherein the flap is movable between first, second and third positions corresponding to the first, second and third flow resistances respectively (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**).

25. **As to claim 24**, Roy teaches a device for enhancing breathing in a patient, the device comprising a mouth piece configured to be held substantially entirely within the patient's mouth and means on the mouthpiece for causing an air flow resistance to expiration that is greater than an air flow resistance to inspiration (**See Figs. 2, 3, 4, 6, See also Col. 2, lines 25-50 and Cols. 4-5**).

26. **As to claim 25**, Roy teaches a device wherein the means for causing an air flow resistance comprises a two-way valve (**See Figs. 4 and 6**).

***Claim Rejections - 35 USC § 103***

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roy (US 4,601,465).

30. **As to claim 11**, Roy teaches essentially all of the limitations except for wherein the body comprises at least one concave channel configured to receive a patient's teeth. Roy, rather teaches elements **15** as shown in Figure 1 to bite onto by a patient's teeth. One of ordinary skill in the art at the time of the invention would expect Roy's device to work equally as well as Applicant's device since both would perform the function of retaining the device in a patient's mouth.



### ***Double Patenting***

31. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

32. Claims 24 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,722,360.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the applicant has received a patent for a species or a more specific embodiment. The patented claim "anticipates" the application claim. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

33. **Claim 24 of the instant application recites**, a device for enhancing breathing in a patient, the device comprising a mouth piece configured to be held substantially entirely within the patient's mouth and means on the mouthpiece for causing an air flow resistance to expiration that is greater than an air flow resistance to inspiration (**See lines 1-8 of claim 5 of patent**). It should be noted that the patent recites additional features not recited in the instant application claim, thereby, making the patent claim more specific than the application claim. As such the patented claim "anticipates" the

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application claim. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

### ***Conclusion***

34. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mital B. Patel  
Primary Examiner  
Art Unit 3743